

OK 9/24/02 *bf***PATENT****IN THE UNITED STATES PATENT AND TRADEMARK OFFICE****In re Application of:** Berry et al.**Serial No.:** 09/497,422**Filed:** February 3, 2000**For:** STABLE NON AQUEOUS SINGLE
PHASE VISCOUS VEHICLES AND
FORMULATIONS UTILIZING SUCH
VEHICLES**Examiner:** B. Fubara**Group Art Unit:** 1615**Attorney Docket No.:** ARC 2914R1Certificate of Transmission under 37
CFR 1.8I hereby certify that this correspondence
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Elizabeth Grannell

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Elizabeth Grannell

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9-24-02**REMARKS**Box AF
Commissioner for Patents
Washington, D.C. 20231

Sir:

The following remarks are filed in response to the Examiner's request for further information regarding the subject matter recited in claims 8-11, 16-18, 21-23, 27-28, which are pending in the present application. Such request was made during a telephone interview with Applicant's undersigned attorney on September 23, 2002.

Claims 8-11 are each directed to viscous, single-phase vehicles that are formulated using components selected from solvent, surfactant, and polymer. The vehicles recited in each of claims 8-11 is non-aqueous, and the viscosity of the viscous vehicles recited in claims 8-11 is between about 1,000 and 10,000,000 poise. The vehicles recited in claims 8-11 may be used to create an active agent formulation by dispersing or suspending a desired active agent (e.g., a protein) throughout a desired amount of viscous vehicle, and the non-aqueous, single-phase and viscous characteristics exhibited by the vehicles recited in claims 8-11 facilitate the preparation of stable active agent formulations suitable for delivering a chosen active agent at a desired rate over an extended period of time. In particular, the non-aqueous, single-phase nature of the vehicles recited in claims 8-11 works to mitigate or eliminate active agent stability issues often encountered with active agent formulations prepared with aqueous vehicles. Moreover, the viscosity of the vehicles recited in claims 8-11 works to reduce settling or agglomeration of the active agent included in an active agent formulation. The vehicles recited in claims 8-11, therefore, serve to maintain a substantially uniform distribution of active agent within an active agent formulation created by dispersing or suspending active agent within such vehicles.

Claims 16-18, 21-23, 27, and 28 recite protein formulations. The formulations recited in claims 16-18, 21-23, 27, and 28 comprise a desired amount of active agent included within "a non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise." Because the protein formulations recited in claims 16-18, 21-23, 27, and 28 are formed by including an amount of active agent within a vehicle that is non-aqueous, single-phase, and viscous, the protein formulations recited in claims 16-18, 21-23, 27 generally exhibit increased stability over time relative to aqueous protein formulations and allow the uniform dispensing of active agent over an extended period of time.

Applicants respectfully submit that each of the claims pending in the present application is in condition for allowance and a notice thereof is respectfully requested. However, if the Examiner has any further questions or concerns that might be resolved by a telephone conference, she is respectfully invited to contact Applicants' undersigned attorney.

Respectfully Submitted,



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Date: September 24, 2002